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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
MARTINELL, JAMES

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/964,956	GERLACH ET AL.	
	Examiner	Art Unit	
	James Martinell	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 38, and 41, drawn to polypeptides, pharmaceutical compositions, and kits classified in class 530, subclass 350.

II. Claims 5-14, 19-21, 39, 42, 46, and 47, drawn to nucleic acids, vectors, host cells, nucleic acid molecular hybridization methods, pharmaceutical compositions, and kits, classified in class 536, subclass 23.5 and class 435, subclasses 320.1, 252.3, 325, and 6.

III. Claims 15-18, 40, and 43, drawn to antibodies, antibody assays, pharmaceutical compositions, and kits classified in class 530, subclass 387.1.

IV. Claims 22 and 23, drawn to polypeptide binding assays, classified in class 435, subclass 7.1.

V. Claim 24, drawn to methods of identifying expression modulation agents, classified in class 435, subclass 7.1.

VI. Claim 25, drawn to methods for modulating activity of a polypeptide using a compound of undisclosed nature, classified in class unknown, subclass unknown.

VII. Claims 26-29 and 48, drawn to methods of treatment using polypeptides, classified in class 512, subclass 12.

VIII. Claims 30-33, drawn to methods of treatment using nucleic acids, classified in class 514, subclass 44.

IX. Claims 34-37 and 49, drawn to methods of treatment using antibodies, classified in class 424, subclass 130.1.

X. Claims 44 and 45, drawn to methods of comparing protein expression, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons. The polypeptides, pharmaceutical compositions containing polypeptides, and kits containing polypeptides of Group I are materially different from, and are therefore independent and distinct from, the

polynucleotides, vectors, host cells, pharmaceutical compositions containing polynucleotides, and kits containing polynucleotides of Group II and the antibodies, pharmaceutical compositions containing antibodies, and the kits containing antibodies of Group III. The polypeptides of Group II are not needed to practice the methods of any one of Groups I-III, V, VI, or VIII-X. The polypeptides of Group I have uses other than in the methods of Groups IV and VII. For example, the polypeptides of Group I may be used in affinity chromatography. The polynucleotides, vectors, host cells, pharmaceutical compositions containing polynucleotides, and kits containing polynucleotides of Group II are materially different from, and are therefore independent and distinct from the antibodies, pharmaceutical compositions containing antibodies, and the kits containing antibodies of Group III. The methods of Group II may be practiced without the antibodies, pharmaceutical compositions containing antibodies, and the kits containing antibodies of Group III. The methods of Group II may be practiced independently of the methods of each one of Groups IV-X. The antibodies, pharmaceutical compositions containing antibodies, and the kits containing antibodies of Group III are not needed to practice the methods of any one of Groups IV-VIII or X. The antibodies, pharmaceutical compositions containing antibodies, and the kits containing antibodies of Group III have uses other than in the methods of Group IX. For example, the antibodies, pharmaceutical compositions containing antibodies, and the kits containing antibodies of Group III may be used in affinity chromatography to isolate proteins. The methods of Groups IV-X may be practiced independently of one another.

Claims 1-4, 15-18, 22-29, 34-38, 40, 41, 43-45, 48, and 49 are drawn to more than one unrelated, independent, and distinct polypeptide or methods requiring the use of more than one unrelated, independent, and distinct polypeptide. Should applicants elect any one or Groups I, III-VII, IX, or X for examination, applicants are further required to select one polypeptide or a set of methods that requires the use of only one polypeptide for examination on the merits.

Claims 5-14, 19-21, 30-33, 39, 42, 46, and 47 are drawn to nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than one individual, independent, and distinct nucleotide sequence in alternative form. Accordingly, these claims

are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (November 19, 1996). This notice permits the examination of from one to ten independent and distinct nucleotide sequences in a single application based upon USPTO resources.

Applicant is required to select no more than ONE of the individual sequences for examination. The search of the no more than ONE selected sequence may include the complement of the selected sequence and, where appropriate, may include subsequences within the selected sequence (*e.g.,* oligomeric probes and/or primers).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

To search any two groups as outlined above would create an undue burden for the U.S. PTO because the searches of the non-patent literature are not only non-overlapping to any appreciable extent, but are also divergent in nature.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1633 at (703) 308-4242. The faxing of such papers must conform to the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and

can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

James Martinell, Ph.D.
Primary Examiner
Art Unit 1631